COVINGTON

BEIJING BRUSSELS DUBAI FRANKFURT JOHANNESBURG
LONDON LOS ANGELES NEW YORK PALO ALTO
SAN FRANCISCO SEOUL SHANGHAI WASHINGTON

Henry B. Liu

Covington & Burling LLP
One CityCenter
850 Tenth Street, NW
Washington, DC 20001-4956
T +1 202 662 5536
hliu@cov.com

Via ECF

March 2, 2022

The Honorable John P. Cronan
Daniel Patrick Moynihan
United States Courthouse
500 Pearl Street
New York, NY 10007-1312

Re: *Clay v. The Procter & Gamble Company*, No. 1:21-cv-11133-JPC-GWG (S.D.N.Y.)

Dear Judge Cronan:

Defendant The Procter & Gamble Company ("P&G") writes to inform the Court that it intends to file a motion to dismiss the Complaint in the above-captioned action. *See* Rule 6.A.

Plaintiff Jacqueline Clay alleges that the label for DayQuil is misleadingly labeled as "non-drowsy" because one of DayQuil's active ingredients—dextromethorphan—can cause drowsiness. Compl. ¶¶ 1-2. Plaintiff asserts that "drowsiness" is a common side effect of dextromethorphan, and it is therefore "misleading to label a product 'Non-Drowsy' . . . if drowsiness is a known side effect of one of its active ingredients." *Id.* ¶¶ 16, 20. Based on that allegation, Plaintiff brings the following claims: (i) violations of the consumer fraud acts of 6 states and the District of Columbia; (ii) violations of New York's General Business Law §§ 349 and 350; (iii) breach of express warranty; and (iv) breach of the Magnuson-Moss Warranty Act (MMWA).

As discussed below, Plaintiff's claims are all barred by the express preemption provision in the Federal Food, Drug, and Cosmetic Act (FDCA) that governs over-the-counter (OTC) drugs. Alternatively, Plaintiff's claims should be dismissed because she fails to plead several essential elements of her claims.

I. Federal law preempts Plaintiff's claims.

The FDCA expressly preempts state law claims that seek to impose requirements that are "different from," "in addition to," or "otherwise not identical" with federal labeling requirements for OTC drugs. 21 U.S.C. § 379r(a). This provision sweeps broadly. As one court in this District has explained, "preemption is certainly appropriate when a state law prohibits labeling that is permitted under federal law. But it is *also* appropriate when a state law prohibits labeling that is *not prohibited* under federal law." *Bowling v. Johnson & Johnson*, 65 F. Supp. 3d 371, 375 (S.D.N.Y. 2014). "The standard, in other words, is not whether a state law actively undermines federal law. It is whether state law diverges from federal law at all." *Id.*; *see also Critcher v. L'Oreal USA, Inc.*, 959 F.3d 31, 35–36 (2d Cir. 2020) (holding that analogous express preemption

provision for cosmetics preempts "*any* state law that provides for labeling requirements that are not *exactly the same* as those set forth in the FDCA and its regulations").

Here, the FDA has issued a comprehensive monograph that sets forth the specific indications, warnings, and directions that must appear on the label for an OTC medication containing dextromethorphan. *See* 21 C.F.R. § 341.74. The monograph does not require P&G to disclose "drowsiness" as a side effect of dextromethorphan, nor does it prohibit P&G from labeling its products containing dextromethorphan as "non-drowsy." On the contrary, the FDA declined to require a drowsiness warning during the monograph process because "[t]he agency is not aware of data demonstrating that the antitussive ingredients codeine and dextromethorphan could be classified as Category I nighttime sleep-aids *or that they require a drowsiness warning*." 48 Fed. Reg. 48,576, 48,589 (Oct. 19, 1983) (emphasis added).

Plaintiff's claims are therefore squarely preempted by Section 379r. Plaintiff's core allegation is that "Non-Drowsy DayQuil Products do not disclose anywhere on their packaging that they do or can cause drowsiness, or that drowsiness is a side effect." Compl. ¶ 13; *see also id.* ¶¶ 2, 14, 16-17, 22. But the FDA expressly considered—and rejected—the contention that drowsiness should be disclosed as a possible side effect of dextromethorphan. Accordingly, "[i]f Plaintiffs were permitted to move forward with their claims, they would be using state law to impose labeling requirements on top of those already mandated in the FDCA and the regulations promulgated thereunder. . . . This is exactly what the FDCA does not permit." *Crichter*, 959 F.3d at 36; *see also Bowling*, 65 F. Supp. 3d at 375 (state law claims are preempted "unless they are *identical* to federal standards" set forth in an FDA monograph); *Bimont v. Unilever U.S., Inc.*, 2015 WL 5256988 at *6 (S.D.N.Y. Sept. 9, 2015) (state law claims are preempted where the FDA's "failure to regulate in this area constitutes strong evidence that the FDA considered the issue . . . and decided that [claim] is insufficiently misleading to warrant regulation").

II. Plaintiff fails to allege that DayQuil's label is misleading.

In addition to Plaintiff's claims being preempted, the Complaint should be dismissed because it fails to plausibly allege that P&G made a false or misleading statement.

First, Plaintiff asserts that DayQuil is misleadingly labeled as "non-drowsy" because dextromethorphan causes drowsiness, but the facts alleged in the Complaint on that issue are paper thin. For example, the principal study cited by Plaintiff finds that "*somnolence was reported for a low percentage of patients*" taking dextromethorphan.[1] Similarly, Plaintiff points to the FDA's adverse event report database to support her claims (Compl. ¶ 18), but the FDA warns that those reports are duplicative, incomplete, unverified, and "do[] not mean that the drug or biologic caused the adverse event."[2] Accordingly, Plaintiff's own factual allegations fail to support

[1] E. Catena and L. Daffonchio, "Efficacy and Tolerability of Levodropropizine in Adult Patients with Non-productive Cough. Comparison with Dextromethorphan," 10 Pulmonary Pharmacology & Therapeutics 89, 89 (1997) (cited at Compl. ¶ 17).

[2] *See* https://www.fda.gov/drugs/questions-and-answers-fdas-adverse-event-reporting-system-faers/fda-adverse-event-reporting-system-faers-public-dashboard.

the inference that dextromethorphan causes drowsiness in consumers. *See Mizel Roth IRA on Behalf of Consol. Asset Funding 3 LP v. Unified Cap. Partners 3 LLC*, 2021 WL 1164439, at *1 (S.D.N.Y. Mar. 25, 2021) ("court need not accept the allegations in the complaint as true" where the materials cited "in the complaint contradict[] allegations in the complaint").

Second, even if Plaintiff had plausibly alleged that dextromethorphan *in isolation* could cause drowsiness, that has no bearing on whether DayQuil—which has other active ingredients—has a similar effect on consumers. DayQuil Severe Cold & Flu, which Plaintiff alleges she purchased, contains three active ingredients other than dextromethorphan: acetaminophen, guaifenesin, and phenylephrine. There are no allegations in the Complaint suggesting that a product with the combination of these four active ingredients causes drowsiness in consumers. In similar circumstances, courts have dismissed lawsuits challenging statements that refer to the whole product when the underlying factual allegations relate solely to a particular ingredient. *See In re GNC Corp.*, 789 F.3d 505, 516–17 (4th Cir. 2015) (affirming dismissal where plaintiffs failed to plausibly allege falsity of the representations regarding the products as a whole).

III. Plaintiff's claims are defective for additional reasons.

In addition to the overarching defects identified above, Plaintiff's individual claims should be dismissed for several independent reasons.

Non-New York Consumer Fraud Claims. Plaintiff, a resident of New York, lacks statutory standing to bring non-New York consumer fraud claims because she has no connection to those states. *See Fishon v. Peloton Interactive, Inc.*, 2021 WL 2941820, at *5 (S.D.N.Y. July 12, 2021).

GBL Claims. Plaintiff's GBL claims are barred by the GBL's "safe harbor" clauses, which provide a "complete defense" to claims challenging advertising that is "subject to and complies with the rules and regulations of" any federal agency. N.Y. Gen. Bus. L. §§ 349(d); 350-d. And Plaintiff does not plausibly allege that she suffered an "actual injury" from her purchase of DayQuil because there are no allegations that P&G charged a premium for DayQuil over other OTC medications that are not marketed as "non-drowsy."

Express Warranty and MMWA Claims. The express warranty claim should be dismissed because Plaintiff failed to provide P&G with timely pre-suit notice, which is a "condition precedent" to any breach of warranty claim. *See Lugones v. Pete & Gerry's Organic, LLC*, 440 F. Supp. 3d 226, 244 (S.D.N.Y. 2020). The MMWA claim should be dismissed because (1) Plaintiff has failed to satisfy the $25 amount-in-controversy requirement for MMWA claims, and (2) the statement "non-drowsy" is not a warranty that is covered by the MMWA. *See*, *Bowling*, 65. F. Supp. 3d at 378 (dismissing MMWA claim because representation on label was not a warranty).

* * *

For the foregoing reasons, P&G intends to move to dismiss the Complaint and proposes the following briefing schedule: P&G will file its motion by March 21, 2022; Plaintiff will file an opposition by April 11, 2022; and P&G will file a reply by April 25, 2022. Alternatively, if Plaintiff intends to amend the complaint, P&G requests that Plaintiff be required to file an amended complaint before P&G moves to dismiss.

Sincerely,

/s/ Henry Liu

Henry Liu*
Covington & Burling LLP
One City Center
850 Tenth Street, NW
Washington, DC 20001
* *Admitted pro hac vice*

Counsel for The Procter & Gamble Company

cc: Counsel of Record (via ECF)